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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,454	12/16/2003	K. Dane Wittrop	97-99E	8855
23713	7590	08/23/2005	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C			GUZO, DAVID	
4875 PEARL EAST CIRCLE			ART UNIT	
SUITE 200			PAPER NUMBER	
BOULDER, CO 80301			1636	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/738,454	Applicant(s) WITTRUP ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 30-97 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-29 is/are allowed.
- 6) ☒ Claim(s) 10, 11, 15, 16, 22, 23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 12-14, 17-21, 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/25/04; 12/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Applicant's election with traverse of Group III, claims 10-21 and SEQ ID NO:24 in the reply filed on 5/20/05 is acknowledged. The traversal is on the ground(s) that Inventions II, III, IV, V, VII, X, XI and XIII are not unrelated because the MPEP (sections 806.04(A) and 808.01) definition of unrelated inventions is not represented in the instant case. Applicants also assert that there would be no burdensome search in searching all of the groups together, at least the groups that are classified in the same class and subclass. Applicants assert that the examiner's reasoning that each of the inventions does not require the particulars of the others for patentability or that the different inventions involve compositions vs. methods where each of the methods is not required for generation of each of the claimed compositions and each of the compositions can be made or used independent of the claimed methods is not a standard for determining whether inventions are independent. With regard to groups reciting products and processes of making or using said products, applicants assert that the claimed products require the methods of making them and therefore should be rejoined. Applicants also indicate that at least, claims 22-29 of Group II should be rejoined to Group III.

This is not found persuasive because of the following reasons: A search of the inventions recited as unrelated would be burdensome. While the claimed inventions are not as divergent as a shoe and a locomotive bearing, as recited in applicants' arguments, the inventions are divergent enough that it would be burdensome for the examiner to search all of the different groups. For example, elected group III (fusion proteins) are unrelated biochemically, structurally and functionally to the DNA

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intermediates coding for mutated polypeptides (Group VII) or DNAs encoding soluble high affinity TCRs (Group XI) or to T cells (XIII), etc. A search of the subject matter of one Group would not be co-extensive with a search of the others and hence would be burdensome. With regard to applicants' assertion that it would not be burdensome to search the different Groups classified in the same Class/subclass, it is noted that a complete search of the invention also involves a search of the extensive non-patent literature and said search of each of the different groups would not be co-extensive with a search of the others. With regard to applicants' assertion that just because a group reciting a claimed composition is related to a group reciting a process of making it in a product by process context, i.e. the product of claim 1 made by the process of claim 2, the groups need to be rejoined, it is noted that the product as claimed must be examined independent of the process by which it is made. A search of the product, which can be made by processes different from the claimed process, would not be co-extensive with a search of the process and would be burdensome. With regard to applicants' assertion that the rationale used by the examiner in restricting the different compositions and methods is not seen in the cited sections of the MPEP, it is noted that the examiner was justifying restriction by indicating that the claimed compositions were unrelated each to the other, that the different compositions were unrelated to the different methods in that the methods are not used to make the compositions and the compositions could be used to make materially different products, etc. This is acceptable rationale for restriction. However, applicants' arguments with regard to

claims 22-29 are persuasive and claims 22-29 will be rejoined to Group III (claims 10-21). Claims 10-29 will be examined.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: Some pages of the specification contain portions which are not readable. Specifically, pages 53, 56, 65-66, 68-79 and 81-92 have portions which are difficult or impossible to read. Applicants are required to submit substitute pages of the specification. Any submission must be accompanied by a statement that no new matter is being added.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Schreuder et al.

Applicants claim in a polypeptide displaying yeast cell, the improvement comprising: a polypeptide fused to a yeast cell wall protein wherein said fused polypeptide is capable of binding a specific ligand; and means for measuring the avidity and specificity of the fused polypeptide binding to said specific ligand.

Schreuder et al. (Yeast, 1993, Vol. 9, pp. 399-409, see whole article, particularly the Abstract, second paragraph of the "Materials and Methods" section on p. 400, third through sixth full paragraphs on p. 401, Fig. 3, pp. 404-405) recites yeast cells comprising a polypeptide (α -galactosidase) fused to a yeast cell wall protein (α -agglutinin) that is capable of binding a specific ligand (X- α -Gal or an antibody capable of binding α -galactosidase); and a means for measuring the avidity and specificity of said binding (i.e. selective plates or immunofluorescence or western blot analysis). Therefore, Schreuder et al. teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 26 is rejected under 35 U.S.C. 102(a) as being anticipated by Schreuder et al.

Applicants' invention is as described above.

Schreuder et al. (TIBTECH, April 1996, Vol. 14, pp. 115-120, see whole article, particularly Figs. 1-5; Table 1; the paragraph bridging pp. 115-116; paragraph bridging pp. 116-117 p. 117 and p. 119) recites yeast cells comprising a polypeptide (α -galactosidase or lipase or single chain antibody fragment, etc.) fused to a yeast cell wall protein (α -agglutinin or flocculin) that is capable of binding a specific ligand (X- α -Gal or an antibody capable of binding α -galactosidase or a lipid, etc.); and a means for

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measuring the avidity and specificity of said binding (i.e. selective plates or immunofluorescence or western blot analysis). Therefore, Schreuder et al. teaches the claimed invention.

Claims 10-11, 15-16, 22-23, 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Boder et al. (Cited by applicants).

Applicants claim a fusion protein displayed on a yeast cell surface, the amino acid sequence of said fusion protein consisting of a polypeptide sequence (which can be a single chain antibody) joined at its N-terminus to the C-terminus of an agglutinin subunit Aga2p sequence, said Aga2p being joined by two disulfide bonds to an agglutinin subunit Aga1p on said yeast cell surface. The fusion protein can also contain an epitope tag between the polypeptide and the Aga2p sequence. Applicants also claim yeast (*Saccharomyces cerevisiae*) displaying said fusion proteins and means for measuring the avidity and specificity of the fused protein binding to the ligand.

Boder et al. (Immunotechnology, Feb 1996, Vol. 2(4), p. 283, Abstract, "Yeast surface display system for antibody engineering") recites a fusion protein displayed on a *S. cerevisiae* cell surface, the amino acid sequence of said fusion protein consisting of a polypeptide comprising a 4-4-20 anti-fluorescein single chain antibody and an epitope tag sequence joined at its N-terminus to the C-terminus of an agglutinin subunit Aga2p sequence. It is noted that the yeast Aga2p subunit is naturally joined to the anchoring subunit Aga1p in the yeast cell wall and hence this limitation would be inherent in the teaching of the Boder et al. reference. Boder et al. also teaches means for determining

the avidity and specificity of the binding of the fused polypeptide to a ligand (i.e. fluorescence activated cell sorting (FACS)). Boder et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague in the recitation of the phrase "...means for measuring the avidity and specificity of the fused polypeptide binding to said specific ligand" because it is unclear what the "means" for accomplishing the recited function encompass and if said "means" are a part of the yeast cell or are separate from the cell and merely encompass any means of measuring the binding of a given ligand to the fused polypeptide on the yeast cell (i.e. the means involve measuring immunofluorescence or determining affinity constants, etc.).

Claims 12-14, 17-21, 24 and 27-29 are free of the art. The closest prior art is exemplified by Schreuder et al. ("TIBTECH" and "Yeast" articles cited above). The prior art teaches yeast cells comprising a polypeptide fused with the yeast cell wall α -agglutinin protein and not the α -agglutinin Aga2p subunit sequence. The prior art does

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not teach or suggest fusions of polypeptides of interest with the a-agglutinin Aga2p subunit.

Applicants, in an Information Disclosure Statement filed 6/25/04, included copies of PTO-892 forms from a patent application. While the references cited on said PTO-892 forms have been considered, applicants are strongly encouraged to cite any future references they wish to make of record on appropriate PTO-1449 (or equivalent) forms.

Claims 11-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 10 recites the amino acid sequence of a fusion protein which **consists of** a polypeptide sequence joined at its N-terminus to the C-terminus of an agglutinin Aga2p sequence. However, claims 11-13 recite a epitope tag sequence between the polypeptide sequence and the Aga2p sequence. Since the amino acid sequence of claim 10 uses closed language (consists of), the presence of an epitope tag sequence between the polypeptide and the Aga2p sequence broadens the claim and hence does not further limit the subject of claim 10.

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Claims 14, 17-21 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claims 27-29 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
August 3, 2005


DAVID GUZO
PRIMARY EXAMINER